JC06 Rec'd PCT/PTO 14 OCT 2005

PTO-1390 (Rev. 07-2005) Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

ATTORNEY'S DOCKET NUMBER TRANSMITTAL LETTER TO THE UNITED STATES 55142.010102 DESIGNATED/ELECTED OFFICE (DO/EO/US) PELICATION NO COM U.S. **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** PRIORITY DATE CLAIMED INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PCT/US2004/011706 15-Apr-2004 15-Apr-2003 TITLE OF INVENTION Medical Device for Monitoring Blood Phenylalanine Levels APPLICANT(S) FOR DO/EO/US Shunnarah, Richard D., May, Sheldon W., Oldham, Charlie D., De Silva, Veronica Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items 3. (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). unexecuted An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 19

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

JC20 Rec'd PET/PTO 1 4 OCT 20

Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

charged

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. U.S. APPLICATION NO. ((6 known, see, 37 GFR) (.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER 552 PCT/US04/011706 55142.010102 20. Other items or information: The following fees have been submitted CALCULATIONS PTO USE ONLY Basic national fee (37 CFR 1.492(a))......\$300 21. 300.00 Examination fee (37 CFR 1.492(c)) 22. 200.00 If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..............................\$0 \$ All other situations.....\$200 100.00 Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)......\$0
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB......\$400 All other situations.....\$500 TOTAL OF 21, 22 and 23 = 600.00 Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra Sheets Number of each additional 50 or fraction RATE thereof (round up to a whole number) - 100 = /50 = x \$250 Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)) CLAIMS **NUMBER FILED NUMBER EXTRA** \$ RATE Total claims 13 - 20 = \$ 50 \$ х 0.00 Independent claims -3 =n \$200 \$ 0.00 MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$ 0.00 TOTAL OF ABOVE CALCULATIONS = 600.00 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½ \$ 300.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). **TOTAL NATIONAL FEE =** \$ Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property TOTAL FEES ENCLOSED = 300.00 Amount to be \$ refunded: Amount to be \$

10/552953

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007, OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

а. 🗀	A check in the amount of \$	_ to cover the abJC20 Recast PCT/PTO 1 4 OCT 2005			
b. X	Please charge my Deposit Account No. 50-1561 A duplicate copy of this sheet is enclosed.	_ in the amount of \$ 300.00 to cover the above fees.			
с. 🗶	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1561. A duplicate copy of this sheet is enclosed.				
d. 🔲	Fees are to be charged to a credit card. WARNING: In be included on this form. Provide credit card information	Information on this form may become public. Credit card information should not nation and authorization on PTO-2038.			
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
Euge Gree 200 l New	LL CORRESPONDENCE TO: ene C. Rzucidlo enberg Traurig LLP Park Avenue York, New York 10166 801 9200	SIGNATURE Eugene C. Rzucidlo NAME 31,900 REGISTRATION NUMBER			

JC20 Rec'd PCT/PTO 1 4 OCT 2009

ERTIFICATE OF MAI	LING BY "EXPRESS MAIL"	' (37 CFR 1.10)	Docket Number	
pplicant(s): Shunnarah, R. e	55142.010102			
Serial No	Filing Date	Examiner	Group Art Unit	
107552953	herewith			
vention: MEDICAL DEVIC	E FOR MONITORING BLOOD PH	IENYLALANINE LEVELS		
,				
nereby certify that the following	ng correspondence:			
1. Transmittal Form PTO 1		•		
 Copy of International Apples Specification (17 pages) 	plication No. PCT/US04/011706 A	2		
4. Abstract (1 page)				
5. Drawings (2 pages)6. Copy of Int'l. Search Rep	oort			
7. Supplemental Amendme				
Unexecuted Declaration Postcard receipt	Power of Attorney			
9. Postcard receipt	(Identify type of co			
	(Identify type of Co	mesponuence)		
October 14, 2	2005	Amy McFall		
(Dute)	(Typed or Printed Name of Pers	son Mailing Correspondence)	
		(Signature of Person Ma	uiling Correspondence)	
		, 0		
		EV 570 899 346 US		
		("Express Mail" Mailing Label Number)		
	Note: Each paper must have it	c own cortificate of mailing		
	Note: Lach paper must have it	s own ceruncate of maning.		